DOMEBORO - aluminum sulfate tetradecahydrate and calcium acetate monohydrate powder, for solution

MOBERG PHARMA NORTH AMERICA LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients (in each packet)	Purpose
Aluminum sulfate tetradecahydrate, 1347 mg	Astringent*
Calcium acetate monohydrate, 952 mg	Astringent*
*When combined together in water, these ingredients form the active ingredient aluminum acetate. See Directions.	

Uses

Temporarily relieves minor skin irritations due to:

- poison ivy
- poison oak
- poison sumac
- insect bites
- athlete's foot
- rashes caused by soaps, detergents, cosmetics, or jewelry

Warnings

For external use only

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- do not cover compress or wet dressing with plastic to prevent evaporation
- in some skin conditions, soaking too long may overdry

Stop use and ask a doctor if condition worsens or symptoms persist for more than 7 days

Directions

- dissolve 1 to 3 packets in a pint (16 oz) of cool or warm water
- stir until fully dissolved; do not strain or filter. The resulting mixture contains 0.16% (1 packet), 0.32% (2 packets), or 0.48% (3 packets) aluminum acetate and is ready for use.

For use as a soak:

- soak affected area for 15 to 30 minutes as needed, or as directed by a doctor
- repeat 3 times a day or as directed by a doctor
- discard solution after each use

For use as a compress or wet dressing:

- soak a clean, soft cloth in the solution
- apply cloth loosely to affected area for 15 to 30 minutes
- repeat as needed or as directed by a doctor
- discard solution after each use

Other information protect from excessive heat

Inactive ingredients dextrin

Questions or comments?

1-800-345-0032 www.domebororelief.com

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PRINCIPAL DISPLAY PANEL

Domeboro®

Aluminum Sulfate Tetradecahydrate / Calcium Acetate Monohydrate as tringent solution

Soothing, Fast, Effective Relief

Of Skin Irritations due to Poison Ivy, Oak, Sumac and Rashes

Reduces redness, rash & blistering

50 YEARS TRUSTED RELIEF

12 Powder Packets

Use as a **soak** or a **compress**

$\mathbf{Domeboro}^{\mathbb{R}}$

astringent solution

Domeboro[®] astringent solution provides soothing, effective relief of minor skin irritations. For over 50 years, **Domeboro**[®] astringent solution has been trusted to help relieve minor skin irritations.

Questions or comments?

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minor skin irritations been trusted to help relieve seu uonnios nuaguurse 50 years, Domeboro® skin irritations. For over effective relief of minor gnirtion provides soothing. Domeboro® astringent

astringent solution

- soak affected area for 15 to 30 minutes as needed, or as dreded by a dootor
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- in same skin compress or well dressing with please to prevent exeporation
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- Uses temporarily releves minor skin intuitors due to
- m.m.m. aufaste betrackschydrake, 952 mg. Calcum aceiste monohydrake, 992 mg. "Afhen combined bogefrer in weder, these ingradients form the active ingredients bu *InsentaA purpose Active ingredients (in each packet)

Drug Facts

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Domeboro[®]

12 Powder Packets

omeboro
astringent solution

Or a compress

astringent solution



Of Skin Irritations due to Poison Ivy, Oak, Sumac and Rashes

Reduces redness, rash & blistering

12 Powder Packets

Domeboro astringent solution

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DOMEBORO

aluminum sulfate tetradecahydrate, calcium acetate monohydrate powder, for solution

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:16864-240
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALUMINUM SULFATE TETRADECAHYDRATE (ALUMINUM CATION)	ALUMINUM SULFATE TETRADECAHYDRATE	1347 mg		
CALCIUM ACETATE MONO HYDRATE (CALCIUM CATION)	CALCIUM ACETATE MONOHYDRATE	952 mg		

	Inactive Ingredients	
	Ingredient Name	Strength
1	Icodextrin	

Product Characteristics				
Color	GREEN (mint green)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:16864-240-01	12 in 1 BOX			
2	NDC:16864-240-10	100 in 1 BOX			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	06/26/2012	

Labeler - Moberg Pharma North America LLC (192527062)

Establishment				
Name	Address	ID/FEI	Business Operations	
Contract Pharmacal Corporation		057795122	MANUFACTURE(16864-240)	

Revised: 6/2014 MOBERG PHARMA NORTH AMERICA LLC